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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

27752 7590 04/12/2005

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/692,634

Applicant(s)

RENNIE ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 20-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2004 has been entered.

Claims 1-9, 20-30 are pending. All rejections of record have been withdrawn in view of the amendment to the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawashima US Patent 5,882,706 or Kaplan US Patent 4,626,541

The instant claims are directed to compositions comprising pyroglutamic acid an organic acid having a dissociation constant value from about 3.0 to about 5.0 wherein the composition is a homogenous liquid solution. Applicant is informed that the instant limitation "providing a surface pH of the nasal cavity tissue from about 3.05 to about 5.5" is not viewed to positively limit the instant composition claims, because once a

Art Unit: 1617

prior art composition contains all elements of the instant claims, it would inherently meet its functional limitations

3. Kawashima teaches drink and other liquid fluids containing water and Japanese apricot vinegar, which falls within the scope of the instantly claimed homogenous liquid solution. (see abstract, col 2, lines 10-65; col 6, lines 1-45). The Japanese apricot vinegar comprises the same organic acid combination as the instant claims 1-4.

Specifically, Japanese apricot vinegar comprise pyroglutamic acid and other organic acids that inherently have dissociation constant values from about 3.0 to about 5.0 such as citric acid, malic acid, succinic acid, formic acid, acetic acid. The amounts of pyroglutamic acid and other organic acid falls within the scope of the instant claims 2, 3, 23. (see col 2, lines 54-60; col 6, lines 1-45). The Japanese apricot vinegar also contains chloride metal salts within the ranges instantly claimed. (see col 2, lines 50-54; col 6, lines 1-13; col 7, lines 22-26). Since Kawashima's compositions contain all elements of the instant claims, they inherently meet the functional limitations and the claimed intended use of the instantly compositions.

4. Kaplan teaches liquid solutions comprising water, pyroglutamic acid, and lactic acid in amounts that fall within the scope of the instant claims prior to . (col 6, lines 6-14 and lines 24-35). Accordingly, for the reasons described above, Kaplan's compositions are capable of performing functional limitations of the instant claims and thus anticipates all the limitations of the instant compositions.

Claims 1-5 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. Yamamoto et al (English Abstract, Eisei Kagaku (1990), 36(4), 332-7).

Yamamoto teaches that commercial vinegar comprise pyroglutamic acid, lactic acid, gluconic acid, and succinic acid in amounts that fall within the scope of the instant claims. Accordingly, the composition instantly claimed is not patentable, because it has been available for public use.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 8-9, 20-25, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto in view of Li, J et al CN 1079259.

The teachings of Yamamoto are described above. Yamamoto teaches that vinegar comprise pyroglutamic acid and a secondary organic acid such as succinic or acetic acid. Yamamoto fails to teach the methods of administering vinegar for treating cold or flu.

Li et al is used to show that edible vinegar can be formulated into a nasal preparation and be administered into nose for treating influenza or common cold. (see abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use the edible vinegars nasally for treatment of cold or flu, because as taught by Li et al, the ordinary skill in the art would have had reasonable expectation of success in treating such condition with nasal formulations of edible vinegar.

Further, more absent a showing of criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to use a suitable carrier system including homogenous liquid or ointment formulation because the pharmacological properties of vinegar is carrier independent.

6. Claims 6-7, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto in view of Li, J et al CN 1079259 as applied to claims 1-5, 8-9, 20-25, 28-30 and further in view Szentmiklosi et al US Patent 5,244,880

The teachings of Yamamoto and Li et al have been described above. Their combined teachings fail to explicitly show the use of a mucoadhesive carbohydrate polymer.

Szentimiklosi discloses that suitable carrier systems for topical compositions can comprise carbohydrate polymers such as carbopol or carbohydrate polymer (see col 5, lines 20-40). Szentimiklosi's topical compositions comprise pyroglutamic acid, an organic acid, a mucoadhesive polymers and even propellants for aerosol delivery of topical formulations (examples 2-9). Szentimiklosi teaches that his aqueous solutions can be prepared conventionally in the form of oleaginous formulations such as ointments, creams, foams or emulsions (col 3, lines 37-41; col 2, lines 29-65; example 8). Further, Examiner takes the position that topical compositions encompass nasal composition, because they are all viewed in the art as topical methods of delivery.

Accordingly, absent a showing of unexpected result, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a mucoadhesive polymer in aqueous solutions of Yamamoto, because as taught by Szentimiklosi, one of ordinary skill in the art would have had a reasonable expectation of success in preparing topical formulations that are specific for any intended site of delivery.

### ***Conclusion***

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**SREENI PADMANABHAN**  
SUPERVISORY PATENT EXAMINER